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HAEMONETICS CORP.,)	
Plaintiff,)	
)	
v.)	Civil Action Nos.
)	05-12572-NMG
FENWAL, INC.,)	09-12107-NMG
Defendant.)	
)	

GORTON, J.

I. Background

On December 22, 2005, Haemonetics, a manufacturer of instruments used to collect and separate blood samples, filed suit ("the '05 Case") against Baxter Healthcare Corp. (later adding Fenwal as a defendant), alleging that Baxter's ALYX Component Collection System ("the ALYX System") infringed U.S.

Patent No. 6,705,983 ("the '983 Patent"), which Haemonetics owns by assignment. The '983 Patent relates to a centrifuge device which separates and collects RBCs from a donor's drawn blood before returning the remaining components to the donor, thus yielding up to double the volume of RBCs from a single donation as compared to manual collection. The device consists of two parts: a vessel in which the blood separation takes place ("the Vessel") and tubing which carries blood in and out of the vessel ("the Tubes").

On July 13, 2007, this Court presided over a Markman hearing regarding the construction of disputed terms, including "centrifugal unit" in Claim 16. Claim 16 of the '983 Patent reads:

A centrifugal unit comprising a centrifugal component and a plurality of tubes, said unit to turn around an axis to separate the components of a liquid, blood in particular, with such plurality of tubes displaying a single tubular component wherein said unit includes:

a base in the form of a disk;

an external cylindrical wall extending from the base;

an internal cylindrical wall extending from the base and separated by the external wall so as to define a ring-shaped separation chamber among each other;

a tubular housing almost extending coaxially to said rotating axis from the base to receive an end of a tubular unit; and

a plurality of channels extending radially in the base of the centrifugal unit, with each channel providing communication between a respective tube of the tubular unit and the separation chamber, with the centrifugal unit having

a radius between 25 and 50 mm and a height between 75 and 125% of the radius.

(emphasis added). The parties agreed that "a centrifugal unit comprising a centrifugal component and a plurality of tubes" meant both the Vessel and the Tubes but they disagreed as to the meaning of the two subsequent references to "centrifugal unit" in the same claim. On August 16, 2007, the Court issued a claim construction order in which it found that the disputed "centrifugal unit" referred to the Vessel only.

Following claim construction and discovery, the case proceeded to a jury trial on Haemonetics' assertions of infringement of Claim 16 only in January, 2009. The Court allowed Haemonetics' motion for Judgment as a Matter of Law ("JMOL") that Claim 16 was not indefinite. The jury returned a verdict for Haemonetics and awarded damages of over \$18 million in lost profits and royalties. The Court subsequently entered a Permanent Injunction and Provisional Royalty requirement.

In August, 2009, Fenwal appealed to the Federal Circuit, arguing that this Court erred in its construction of "centrifugal unit" on Claim 16 and in allowing JMOL that Claim 16 was not indefinite. In June, 2010, the Federal Circuit concluded, contrary to this Court's construction, that "centrifugal unit" in Claim 16 "consistently means a vessel and a plurality of tubes." Haemonetics Corp. v. Baxter Healthcare Corp., 607 F.3d 776, 783 (Fed. Cir. 2010). The Federal Circuit vacated this Court's JMOL

and remanded for further proceedings, specifically for a determination of 1) the meaning of "radius" and "height" under the correct claim construction of "centrifugal unit" and 2) whether claim 16 is definite. The Federal Circuit also vacated the jury verdict and award of prospective remedies because it necessarily relied on the incorrect claim construction. Haemonetics' petition for rehearing en banc was denied on August 13, 2010, and the Federal Circuit issued its judgment as a mandate on August 20, 2010.

B. The '09 Case

During the pendency of the appeal in the '05 case and in light of the injunction entered, Fenwal designed a new version of its product that it believed avoided infringement of the '983 Patent. On December 14, 2009, Haemonetics commenced a new action against Fenwal ("the '09 Case") seeking a declaration that Fenwal's redesigned separation cup continued to infringe the '983 Patent.

In September, 2010, following the remand of the '05 Case by the Federal Circuit to this Court, Haemonetics filed its infringement contentions, alleging that the "plurality of tubes" are not contained in the umbilicus but rather within the Vessel itself. Haemonetics also moved for a status conference which the Court denied because, inter alia, the parties already had a stipulated and shared understanding of the construction of

"plurality of tubes" as meaning "two or more conduits that transport liquid materials (e.g. blood and blood components) into and out of the vessel." The Court further noted that the doctrine of judicial estoppel prevented Haemonetics from asserting a different construction of "plurality of tubes."

On November 12, 2010, Fenwal moved for summary judgment in both the '05 Case and '09 Case, contending that 1) neither its original nor redesigned products infringe Claim 16 of the '983 Patent either literally or under the doctrine of equivalents and 2) Claim 16 is invalid for indefiniteness. Haemonetics filed an opposition in the '09 Case only but the Court treats both of defendant's motions for summary judgment as opposed. Fenwal further filed a reply in both cases. Defendant's motions for summary judgment in both cases remain pending before the Court.

II. Analysis

A. Legal Standard

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991) (quoting Garside v. Osco Drug, Inc., 895 F.2d 46, 50 (1st Cir. 1990)). The burden is on the moving party to show, based upon the pleadings, discovery and affidavits, "that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ.

P. 56(c).

A fact is material if it "might affect the outcome of the suit under the governing law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "Factual disputes that are irrelevant or unnecessary will not be counted." Id. A genuine issue of material fact exists where the evidence with respect to the material fact in dispute "is such that a reasonable jury could return a verdict for the nonmoving party." Id.

Once the moving party has satisfied its burden, the burden shifts to the non-moving party to set forth specific facts showing that there is a genuine, triable issue. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). The Court must view the entire record in the light most hospitable to the non-moving party and indulge all reasonable inferences in that party's favor. O'Connor v. Steeves, 994 F.2d 905, 907 (1st Cir. 1993). If, after viewing the record in the non-moving party's favor, the Court determines that no genuine issue of material fact exists and that the moving party is entitled to judgment as a matter of law, then summary judgment is appropriate.

B. Application

Fenwal argues that 1) neither its original nor redesigned products infringes Claim 16 of the '983 Patent either literally or under the doctrine of equivalents and 2) Claim 16 is invalid for indefiniteness. The Court turns first to the issue of

noninfringement.

1. Noninfringement

An infringement analysis requires 1) the Court to determine, as a matter of law, the meaning and scope of the patent claims asserted to be infringed and 2) the trier of fact to compare the properly construed claims to the device accused of infringing.

Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). Summary judgment of noninfringement is appropriate where, "on the correct claim construction, no reasonable jury could have found infringement on the undisputed facts or when all reasonable factual inferences are drawn in favor of the patentee." Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1353 (Fed. Cir. 2001).

The Federal Circuit has held, in reversing the judgment entered in this Court, that "centrifugal unit" in Claim 16 "consistently means a vessel and a plurality of tubes." Haemonetics, 607 F.3d at 783. The height and radius limitations stated in Claim 16 apply, therefore, to the combined "vessel" and "plurality of tubes." The Federal Circuit further explained:

The '983 Patent describes a centrifugal device comprising 1) a vessel in which blood components are separated in a separation chamber and 2) tubing through which blood flows in and out of the vessel. The tubing connects the spinning vessel to a non-rotating support structure, forming a question mark-shaped loop around the vessel.

Id. at 778-79. As this Court previously noted, the parties have a stipulated and shared understanding of the construction of

"plurality of tubes" as meaning "two or more conduits that transport liquid materials (e.g. blood and blood components) into and out of the vessel."

Haemonetics acknowledges, as it must, that the question mark-shaped loop, or umbilicus, is a "plurality of tubes." It also concedes that when the umbilicus is included within the height and radius limitations of Claim 16, i.e. a radius between 25 and 50 mm and a height between 75% and 125% of the radius, neither the defendant's original nor its redesigned products, which have a radius of approximately 70 mm and a height of approximately 150 mm (or approximately 214% of the radius), infringes the '983 Patent, either literally or under the doctrine of equivalents.¹ Summary judgment in defendant's favor is, therefore, appropriate.

Haemonetics contends, however, that while the umbilicus is a "plurality of tubes," it is not the only "plurality of tubes." In light of the Federal Circuit's mandate, Haemonetics reexamined the devices and purportedly identified an additional "plurality of tubes" molded into the "centrifugal unit." Because these so-called "Centrifugal Tubes" are internal to the "centrifugal

¹ The Federal Circuit remanded the '05 Case to this Court for, inter alia, a determination of the meaning of "radius" and "height" within Claim 16. Although Haemonetics disputes Fenwal's measurements in the Statement of Undisputed Material Facts, the argument advanced by Haemonetics with respect to measurement is premised entirely on its contention that the "Centrifugal Tubes" constitute an alternative "plurality of tubes." Moreover, Haemonetics concedes that the umbilicus, as the "plurality of tubes", "evades infringement."

unit", their dimensions are coterminous with those of the "centrifugal component." Plaintiff argues that nothing in the '983 Patent limits Claim 16 to devices with only a single "plurality of tubes" and therefore:

The fact that the ALYX Cups have more than one "plurality of tubes", one of which may now evade infringement (umbilicus) and one which does not (Centrifugal Tubes), does not make them any less infringing.

For an abundance of reasons, plaintiff's argument fails. First, according to the stipulated construction, a "plurality of tubes" means "two or more conduits that transport liquid materials (e.g. blood and blood components) into and out of the vessel." (emphasis added). According to plaintiff, the "Centrifugal Tubes" are contained entirely within the Vessel. Because the "Centrifugal Tubes" can transport blood only within, rather than "into and out of", the Vessel, the "Centrifugal Tubes" do not constitute a "plurality of tubes."

Second, "centrifugal unit" in Claim 16 is comprised of two distinct structures: a "vessel" and a "plurality of tubes." The Federal Circuit had decided that the preamble to Claim 16 "unambiguously defines 'centrifugal unit' as 'comprising' two structural components: a centrifugal component and a plurality of tubes." Id. at 781 (emphasis added). In addition, the Federal Circuit concluded that:

This court lacks any evidence in the record or any argument by the parties directed to where the height or radius are to be measured when the centrifugal unit includes not only the circular vessel but also the off-set, question mark-shaped tubes.

Id. at 784 (emphasis added). If, as plaintiff contends, the "plurality of tubes" is part of the "centrifugal component", then, as defendant argues, "this claim language, which requires a vessel and a plurality of tubes would be rendered a cipher." The "plurality of tubes" must, therefore, be external to the Vessel itself. The prosecution history, drawings and written descriptions of the '983 Patent further support that conclusion.

Finally, throughout this protracted litigation, both parties have consistently identified the "plurality of tubes" as the umbilicus. As the Court stated in its Memorandum & Order dated October 13, 2010, the doctrine of judicial estoppel prevents Haemonetics from now asserting a different construction of "plurality of tubes."

The Court, therefore, rejects plaintiff's contention that the umbilicus is not the only "plurality of tubes." Haemonetics does not dispute that when the umbilicus, as the "plurality of tubes", is included within the height and radius limitations of Claim 16, Fenwal's products do not infringe the '983 Patent, either literally or under the doctrine of equivalents. The Court will, therefore, allow summary judgment in Fenwal's favor in both the '05 and '09 Cases.

2. Indefiniteness

Fenwal further contends that summary judgment should be allowed in its favor because Claim 16 is invalid for indefiniteness. Because the Court finds that neither of Fenwal's devices infringes the '983 Patent, the Court declines to reach the issue of indefiniteness.

ORDER

In accordance with the foregoing,

- 1) defendant's motion for summary judgment in the '05 case (Docket No. 371) is **ALLOWED**; and
- 2) defendant's motion for summary judgment in the '09 case (Docket No. 66) is **ALLOWED**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated September 13, 2011